

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

For: **NOVEL RECEPTORS**

Atty. Dkt. No. 006539.00146

REPLY BRIEF

Sir:

The Examiner's Answer was mailed March 31, 2006. We believe this Reply Brief is timely filed. If a fee is due, please charge our Deposit Account No. 19-0733.

A paper regarding the Request for Oral Hearing accompanies this Reply Brief.

Status of Claims

Claims 1-5 and 8-31 are canceled. Claims 6 and 7 are rejected.

Grounds of Rejection to be Reviewed on Appeal

Whether the subject matter of claims 6 and 7 has patentable utility under 35 U.S.C. § 101 and is enabled under 35 U.S.C. § 112 ¶ 1.

Argument

This Reply Brief is filed to address one point in the Examiner's Answer regarding the post-filing date publication He *et al.*¹

The appealed claims are directed to isolated nucleic acids encoding a polypeptide comprising an amino acid sequence of SEQ ID NO:2. SEQ ID NO:2 encodes a mouse G protein-coupled receptor termed "TGR18." The specification teaches, *inter alia*, that TGR18 is abundantly expressed in the kidney (*e.g.*, page 7, lines 7-9); and that TGR18 can participate in the modulation of cellular function in cells, for example kidney cells, in which it is expressed (*e.g.*, page 51, lines 31-34). The specification also discloses that a GPCR that is predominantly expressed in the kidney can play a role in renal disease, *e.g.*, hypertension (*e.g.*, page 52, lines 2-6) and in modulating kidney cell function (*e.g.*, page 7, lines 7-8 and 12-14).

To further support the utility of the claimed nucleic acids, Appellant provided He *et al.*, which demonstrates that TGR18 has biological activity in kidney function. The Examiner's Answer contends that He *et al.* is evidence that Appellant's invention was not complete at the time of filing but required more research to determine how to use it. Page 8 of the Examiner's Answer.

He *et al.* merely provides additional data demonstrating the biological relevance of TGR18 in the kidney and was provided to support the specification's assertion of utility, a fact which the Examiner questions. Submission of post-filing date evidence is proper for this purpose. *In re Langer*, 503 F.2d 1380, 1391, 183 U.S.P.Q. 288, 297 (C.C.P.A. 1974); *In re Marzocchi*, 439 F.2d 220, 223, 169 U.S.P.Q. 367, 370 n. 4 (C.C.P.A. 1971).


¹ *Nature*, 429:188-193, 2004; Exhibit 3 of the Evidence Appendix of Appellant's Brief on Appeal.

In view of the biological role of TGR18 and its demonstrated GPCR function, as shown by the evidence of record, including He *et al.*, TGR18 nucleic acid and polypeptides sequences have credible, substantial, and specific uses.

Respectfully submitted,

BANNER & WITCOFF, LTD.

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By: 
Lisa M. Hemmendinger
Registration No. 42,653

Customer No. 22907